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10/725,473	12/03/2003	Mark Zoller	67824.407404	5602

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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/725,473	ZOLLER ET AL.	
	Examiner	Art Unit	
	ROBERT LANDSMAN	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *13 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *194-233* is/are pending in the application.

4a) Of the above claim(s) *215* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *194-214 and 216-233* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 January 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

A. Claims 194-233 are pending. Claim 215 recites SEQ ID NO:4, a non-elected SEQ ID NO. Therefore claims 194-214 and 216-233 are the subject of this Office Action.

2. Specification

A. Though none could be found, Applicant is advised that embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I regarding incorporation by reference.

B. Though none could be found, trademarks should be capitalized wherever they appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

C. Though none could be found, any U.S. or Foreign Applications cited in the specification which have since issued should be updated with the corresponding Patent No.

2. Claim Objections

A. Claims 199-204 and 210-215 are objected to since the term "exhibits" should be replaced with "has" or "is" in claims 199-204, which is a term more commonly used in patent claims. Similarly, claims 210-215 are objected to since the term "possesses" should be replaced in a similar manner. At the very least the term should be identical, such as "possesses" since "exhibits" is not clearly defined.

B. Claims 209-212 are objected to since the first letter in "sequence" should be lower case to be consistent with the other claims.

C. Claim 217 is objected to for depending from a canceled claim.

3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 194-233 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of producing the heterodimer of SEQ ID NO:5 and 7 (encoded by SEQ ID NO:8 and 9), or the specific human and rat T1R1 and T1R3 disclosed in Figure 1, does not reasonably provide enablement for methods of producing all umami taste receptors, including those which hybridize to SEQ ID NO:8 or 9, or for fragments thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

First, the breadth of the claims is excessive with regard to claiming methods of producing all heteromeric T1R1/T1R3 taste receptors which are activated by umami taste, including those from **any and all species**. Applicants have only identified SEQ ID NO:5 and 7 can form dimers and are activated by umami taste. In addition, Applicants are claiming mouse T1R1 and T1R3 receptors (e.g. claim 195). However, these receptors do not appear to be disclosed in the instant application. Only the human and rat T1R1 and T1R3 receptors of Figure 1, and SEQ ID NO:5 and 7 id these are distinct from those in Figure 1, are enabled.

Similarly, the breadth is excessive with regard to taste receptors encoded by nucleic acid sequences which "**hybridize**" under stringent conditions to that of SEQ ID NO:8 or 9, as well as "**fragments**" thereof of the receptors, or proteins "**at least 90% identical**" to SEQ ID NO:5 or 8. Nucleic acid molecules which "hybridize" to those polynucleotides would have one or more nucleic acid substitutions, deletions, insertions and/or additions to said polynucleotides. Similarly, proteins which are

"90% identical" or "fragments" of the claimed proteins would have one or more amino acid substitutions, deletions, insertions and/or additions to the claimed proteins.

Applicants provide no guidance or working examples of nucleic acid molecules which hybridize to SEQ ID NO:8 or 9, or of proteins which are "fragments" of these proteins. Furthermore, it is not predictable to one of ordinary skill in the art how to make a functional T1R1/T1R3 heterodimer other than that comprising the full-length SEQ ID NO:5 and 8. No fragments of either SEQ ID NO:5 or 8, or of the nucleic acid molecules which encode them, have been disclosed which can produce a functional umami taste receptor.

In summary, the breadth of the claims is excessive with regard to Applicants claiming all nucleic acids which hybridize to SEQ ID NO:8 or 9, or for proteins which are fragments of these proteins and can form a functional umami taste receptor. There is also a lack of guidance and working examples of these nucleic acid molecules and proteins. These factors, along with the lack of predictability to one of ordinary skill in the art as to how to make a functional T1R1/T1R3 heterodimer other than that comprising the full-length SEQ ID NO:5 and 8 leads the Examiner to hold that undue experimentation is necessary to practice the invention as claimed.

4. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 194-233 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. The specification only describes screening methods using the T1R1/T1R3 heterodimer comprising SEQ ID NO:5 and 8, as well as for the human and rat T1R1 and T1R3 receptors disclosed in Figure 1. Heterodimers from **any other species**, including the mouse receptors of claim 195, or "**fragments**" of SEQ ID NO:5 or 8, as well as those "**at least 90% identical**" to SEQ ID NO:5 or 8, would have one or more amino acid substitutions, deletions, insertions and/or additions to these proteins and have not been described. Similarly, nucleic acid molecules which "**hybridize**" to those polynucleotides of SEQ ID NO:8 or 9 would have one or more nucleic acid substitutions, deletions, insertions and/or additions to said polynucleotides. Similarly, Applicants have not described which residues are critical for protein function

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the nucleic acid or protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO:5, 7, 8 and 9, or molecules which hybridize to the polynucleotides of SEQ ID NO:8 or 9 (which could be at least thousands of molecules), alone, are insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

5. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 196 and 197 are confusing since the term “same species origin” implies that all that is required is that the receptors are initially from a species, but can be altered. In other words, it is not clear why the term "origin" is used. It implies that receptor can somehow be altered, or a derivative, as opposed to simply saying "are of the same (or different) species.”

B. Claims 198-217 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “contained in” is unclear. It is not understood if the claim refers to the full-length of the claimed SEQ ID NO, or a fragment thereof which encodes the functional receptor, for which the specification has not described. As written, it appears that the T1R1 receptor is some subsequence of SEQ ID NO:5 and, furthermore, that there is only one subsequence in SEQ ID NO:5 (i.e. "the sequence contained in"). It is suggested that the phrase “contained in” be replaced with, for example, “of.”

C. Claims 206, 207 and 217 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "in association with" is unclear. It is not understood in what manner T1R1 is "in association with" T1R3.

D. Claim 206 and 217 is vague and indefinite since the claim recites "stringent conditions." It is not known what these conditions are. Nucleic acid molecules which hybridize under conditions of "low" stringency would not necessarily hybridize under conditions of "high" stringency. Furthermore, not all conditions of "high" or "low" stringency, for example, are the same. Therefore, it is required that Applicants amend the claims to recite the exact hybridization conditions without using indefinite phrases such as "*for example*" **without adding new matter**.

E. Claim 217 is unclear since it is not understood how the receptor "responds" to sweet taste stimuli. In other words, the term is not defined, nor is it clear what specific response is expected.

F. Claim 229 is confusing since it is unclear how the sequences are "attached."

6. Obviousness-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 194-214 and 216-233 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-35 of U.S. Patent No. 7,301,009; claims 1-61 of 7,309,577 and claims 1-64 of 7,303,886. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application recites a method of producing a T1R1/T1R3 taste receptor. The '009 patent claims the T1R1/T1R3 heteromeric taste receptor. The '577 patent claims a binding assay using the T1R1/T1R3 heterodimer. The '886 patent recites a methods of screening using T1R1/T1R3 dimer. Methods of making the heterodimer is obvious over the isolated heterodimer itself since, in order to obtain the heterodimer, it must be produced, and expressing the nucleic acid sequences encoding this receptor would have been obvious to the artisan at the time of the instant invention. Furthermore, in order to and using the dime, again, it must be produced

These method claims could not be found in restricted parent application 10/179,373 or 09/897,427.

B. Claims 194-214 and 216-233 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 194-198, 200, 202-209, 211-218, 220-234 and 254-277-229 of copending Application No. 10/725,489. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application recites a method of producing a T1R1/T1R3 heterodimeric taste receptor. The '489 application recites a cell expressing this heteromer. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used recombinant cells to produce the heterodimer claimed in the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. However, the claims in '489 have been allowed.

Again, these method claims could not be found in restricted parent application 10/179,373 or 09/897,427.

7. Prior Art

A. No art rejection is being made since, even though the claimed sequences may have been known at the time of filing of the instant application (e.g. US20030036089), no prior art reference teaches the claimed T1R heterodimers, or that they modulate umami taste. It is noted that the present invention is only being given priority to 09/897,427 (July 3, 2001).

8. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman, Ph.D. whose telephone number is (571) 272-0888. The examiner can normally be reached on M-F 10 AM – 6:30 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert Landsman/
Primary Examiner, Art Unit 1647